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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,246	12/06/2001	Robert Sixto JR.	SYN-064C	5866
24131	7590	06/23/2004	EXAMINER	
LERNER AND GREENBERG, PA P O BOX 2480 HOLLYWOOD, FL 33022-2480			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/010,246

Applicant(s)

SIXTO ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 18 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 21-28 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/06/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5-10, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,851,359 to Wilson. Wilson discloses a clip with a first arm (10a), a second arm (10b), and a bridge (10c) connecting the two arms forming a U-shaped structure. Wilson's clip has a flexible, deformable retainer (11) [Column 2, lines 10-17]. The retainer (11) has a length of approximately  $\pi$  times the distance between the two arms when the arms are parallel. Using a ruler to measure the relative dimensions, the distance between the two arms is 9.5 mm, and the length (longitudinally) of the retainer is 18.5 mm. Another length of the retainer (measured across the longest dimension of the retainer) is 22.5 mm. Two times is considered to be "at least approximately" 3.1415 times.
2. Regarding Claims 5, 6, 8, and 9, Wilson discloses a retainer (11), which is decouplable from the arms (10 & 10b) [Column 3, lines 34-40]. The fitting, as shown in Figure 7, is a friction fit: friction (among other forces) prevents the head (10e) of the arm (10b) from disengaging.
3. Regarding Claim 7, Wilson discloses the invention as claimed. The deformable retainer (11) can be thought of as two separate retainers, each of which is extending

from the respective arms (10a and 10b). The retainers are of equal length, and each has a sharp tip, as shown in Fig. 7. Shown in Fig. 6 is the fitting on each retainer, and the sharp edges adjacent components 11d and 11c.

4. Regarding Claim 10, Wilson discloses a clip with two arms. Each arm includes an end portion defining a slot (10f & 10d) [Column 2, lines 60-65]. The retainers (11- two sides) have a proximal portion, which has a friction fit with each respective slot [Figures 3 and 7].
5. Claims 1, 2, 4, 5, and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,575,802 to McQuilkin et al. McQuilkin discloses a surgical clip with a first arm (12), a second arm (142), and a U-shaped bridge (16) connecting them [see Fig. 1; Column 1, lines 55-67]. McQuilkin discloses a deformable retainer (deformable particularly at hinge 144) extending from arm (142). The deformable retainer (140/144/126/128) has a length greater than  $\pi$  times the distance between the arms when the arms are substantially parallel [as shown in Fig. 2]. The distance between the arms is 2 mm [Column 3, line 11], and the length of the retainer portion (140), as measured from the hinge in an arcing trajectory to the edge (152) is significantly greater than 3 times the distance between the parallel arms. Examiner estimates that the length of the retainer portion (140) is 11 mm.
6. Regarding Claims 2 and 23, McQuilkin discloses a surgical clip with a retainer having a thickness smaller than the thickness of the first arm. The thickness of the retainer is measured at hinge (144). The first arm has a thickness of 3 mm and the

Art Unit: 3731

hinge portion of the retainer has a thickness of 1mm [Column 3, lines 10 and 13; Fig. 2].

7. Regarding Claim 4 and 25, McQuilkin discloses a retainer with a sharp tip. Retainer portion (140) has a sharp tip at tooth (150) and retainer portion (126/128) has a sharp tip at tooth (126).
8. Regarding Claims 5 and 26, McQuilkin discloses a retainer that is decouplable from one of the arms. If one were to disassemble hinge (16), then one would sever one arm from the other, decoupling the first arm (12) from the retainer (140).
9. Claims 1, 5, 6, 22, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 2,246,495 to Alessi, et al. Regarding Claim 1, Alessi discloses a clip capable of use in surgery with two arms (11, 12) and a U-shaped bridge (10) between them. There is a deformable retainer (16/21/15) extending between the arms that has a length of greater than 3 times the distance between the arms, as shown in Fig. 3. The retainer includes a deformable spring member (21) [Column 2, lines 24-34].
10. Regarding Claims 5, 6, and 27, Alessi's retainer (17/21) is decouplable from one of the arms. Arm (11) is attached to the tubular member (16) via a lug (19) in a slot (20) [Column 2, lines 15-20]. The aforementioned lug is merely a nut screwed on (involving friction) to arm (31).
11. Claims 17 and 18, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,430,997 to DiGiovanni et al. DiGiovanni discloses a multiple clip

applier for applying clips as disclosed by the applicant. DiGiovanni's clips (11) each have a first arm, a second arm, and a U-shaped bridge connecting them. Each clip has a deformable ("deflectable") retainer at its end [Column 4, lines 46-54]. Each retainer has a length of at least  $\pi$  times the distance between the arms when the arms are substantially parallel, as shown in Figure 5A. As is observable from Fig. 5A, the average distance between the two arms is much less than the length of the retainer, as measured perpendicular from the longitudinal axis of the clip [see Attachment #1].

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 3, 22, 23, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Publication No. US 2002/0104199 A1 to Chen. Chen discloses a first arm, a second arm, a U-shaped bridge connecting them, and deformable retainers extending from each arm, as labeled in Attachment #2. Since the clip is made out of "metal wire" the whole clip can be characterized as deformable. The clip is of a similar construction to the common paper clip, which is commonly known to be

easily bendable. No structure is given to the word “retainer” in claim 1, and therefore anything that is capable of retaining something can be considered a retainer. Each retainer (labeled in Attachment #2) has a sharp tip. The deformable retainers each have a length more than 3.14 times the distance between the first arm and the second arm.

### *Response to Arguments*

13. Applicant's arguments filed 04/06/2004 have been fully considered but they are not persuasive. With regards to the Wilson reference (U.S. Patent No. 3,851,359), retainer 11 is certainly deformable because it is made out of plastic [Column 2, lines 10-13]. Plastic is generally considered to be a deformable material. It is relatively more deformable than metal arms 10a and 10b. More specifically, in Column 2, lines 14-17, Wilson says specifically that the retainer 11 is made out of a plastic “possessing a measure of resiliency.” Therefore, the whole head is (to some degree) deformable, not just deformable flap 11c, as asserted by the Applicant (“Remarks”, page 12).

Further regarding Wilson, using a ruler to measure the relative dimensions in Fig. 4, the distance between the two arms is 9.5 mm, and the length (longitudinally) of the retainer is 18.5 mm. Another length of the retainer (measured across the longest dimension of the retainer) is 22.5 mm. Two times (or 2.37 times) is considered to be “at least approximately” 3.1415 times. Furthermore, comparing Wilson’s Figure 4 to Applicant’s Figure 18: in Wilson’s Fig. 4, one could measure a *circumferential length of the outside of the retainer 11* and say that this length is substantially the

same as the length of the circumferential length of the retainer in Applicant's Fig. 18.

Retainer 11 is "at least approximately" semi-circular and will therefore have a circumference of some multiple of Pi.

14. Applicant's arguments filed 04/06/2004 have been fully considered but they are also not persuasive with regards to U.S. Patent No. 5,575,802 to McQuilkin et al. Applicant asserts, "the distance between the jaws 12, 14 is equal to zero" ["Remarks", page 13]. Examiner disagrees. Jaws ("arms") 12, 14 are *distinct components* from liners 18, and 20 [Column 1, lines 55-57]. Applicant does not limit the claims with language saying that there is an open space between the two arms. Examiner maintains that there is a distance between McQuilkin's two arms 12, 14, and that distance is equal to the space taken up laterally by the liners 18 and 20. Figure 2 shows the arms 12, 14 in a parallel arrangement.
15. Applicant's arguments filed 04/06/2004 have been fully considered but they are also not persuasive with regards to U.S. Patent No. 2,246,495 to Alessi et al. The spring is a part of retainer 16/21/15. The whole assembly 16/21/15 is considered to be the retainer extending from arm 11.
16. Applicant's arguments filed 04/06/2004 have been fully considered but they are also not persuasive with regards to U.S. Patent No. 4,430,997 to DiGiovanni et al. Figure 5A shows that there is some distance between the two arms of the clip while the arms are substantially parallel (as the arms *are* in Figure 5A). Even if this distance were zero, then the prior art would still read on the claimed invention:



Art Unit: 3731

Length of the retainer  $> \pi \times$  distance between the arms

(some positive value)  $> 3.1415 \times$  zero

(some positive value)  $>$  zero

However Examiner maintains that if the clip can be used to ligate something like an artery or a blood vessel [Column 2, lines 36-40], then there is some positive, nonzero distance between the two arms of the clip.

*Allowable Subject Matter*

17. Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

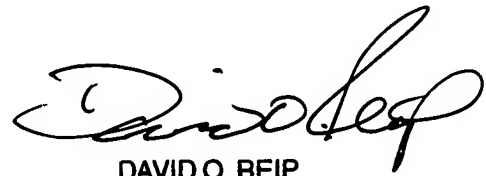
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP  
BCP  
June 17, 2004

  
DAVID O. REIP  
PRIMARY EXAMINER